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EPAR summary for the public

Conbriza

bazedoxifene

This is a summary of the European public assessment report (EPAR) for Conbriza. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Conbriza.

What is Conbriza?

Conbriza is a medicine that contains the active substance bazedoxifene. It is available as tablets (20 mg).

What is Conbriza used for?

Conbriza is used for the treatment of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause. It is used in women who are at risk of fracture (broken bones). Conbriza has been shown to significantly reduce fractures in the spine but not in the hip.

The medicine can only be obtained with a prescription.

How is Conbriza used?

The recommended dose of Conbriza is one tablet once a day. Patients should also receive calcium and vitamin D supplements if they do not get enough from their diet.

How does Conbriza work?

Osteoporosis happens when not enough new bone grows to replace the bone that is naturally broken down. Gradually, the bones become thin and fragile, and more likely to break (fracture). Osteoporosis is more common in women after the menopause, when the levels of the female hormone oestrogen fall: oestrogen slows down bone breakdown and makes the bones less likely to fracture.

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The active substance in Conbriza, bazedoxifene, is a selective oestrogen receptor modulator (SERM). Bazedoxifene acts as an 'agonist' of the oestrogen receptor (a substance that stimulates the receptor for oestrogen) in some tissues in the body. Bazedoxifene has the same effect as oestrogen in the bone.

How has Conbriza been studied?

Conbriza has been compared with raloxifene (another medicine used to treat osteoporosis) and placebo (a dummy treatment) in one main study involving about 7,500 women with osteoporosis who had been through the menopause. All of the women in the study were also given calcium and vitamin D supplements. The main measure of effectiveness was the number of new spine fractures over three years.

Conbriza was also compared with raloxifene and placebo in another main study involving 1,583 postmenopausal women who were considered to be at risk of osteoporosis. The women were treated for two years and received calcium supplements. The main measure of effectiveness was the change in bone density (a measure of how strong the bones are) in the spine after two years of treatment.

What benefit has Conbriza shown during the studies?

In the first study, Conbriza was more effective than placebo at reducing the number of new spine fractures. After three years, 2% of the patients receiving Conbriza (35 out of 1,724) had new fractures compared with 4% of those receiving placebo (59 out of 1,741). The difference was more relevant in the sub-group of women at higher risk of fractures before the study. Conbriza was not shown to be effective at reducing the number of fractures outside the spine.

In the other study, Conbriza was also more effective than placebo at maintaining the bone density of the spine. After two years, the average bone density remained almost unchanged in women who received Conbriza, but in women who received placebo it was reduced by over 1%.

In both main studies the effects of Conbriza were similar to the effects of raloxifene.

What is the risk associated with Conbriza?

The most common side effects with Conbriza (seen in more than 1 patient in 10) are hot flushes, muscle spasms and peripheral oedema (swelling, especially of the ankles and feet). For the full list of all side effects reported with Conbriza, see the package leaflet.

Conbriza must not be used in women who have had venous thromboembolism events (problems due to the formation of blood clots in the veins) including deep vein thrombosis (a blood clot in a deep vein, usually in the leg), pulmonary embolism (a blood clot in the lungs) and retinal vein thrombosis (a blood clot at the back of the eye). It must not be used in women with unexplained bleeding from the womb and women with signs or symptoms of endometrial cancer (a cancer of the lining of the womb). Conbriza is only for use in women who have been through the menopause, so it must not be used in women who could become pregnant. For the full list of restrictions, see the package leaflet.

Why has Conbriza been approved?

The CHMP decided that Conbriza's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Conbriza?

A risk management plan has been developed to ensure that Conbriza is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Conbriza, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Conbriza

The European Commission granted a marketing authorisation valid throughout the European Union for Conbriza on 17 April 2009.

The full EPAR for Conbriza can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Conbriza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2015.